CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40353

CORRESPONDENCE

MALLINCKRODT

Mallinckrodt Inc. 675 McDonnell Boulevard PO Box 5840 St. Louis, MO 63134 Phone: 314-654-2000 www.mallinckrodt.com

FAX AMENDMENT TO A PENDING APPLICATION

March 30, 2000

NDA [illegible]
NC to FA

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Attention: Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

RE: ANDA 40-352: Meperidine Hydrochloride Tablets, USP (50 mg and 100 mg)
CHEMISTRY, MANUFACTURING, AND CONTROL INFORMATION

Dear Sir or Madam:

The following information is provided in response to the March 24, 2000 facsimile letter from the Agency in reference to ANDA 40-352 submitted December 23, 1998.

For ease of reference, the entire amendment is numbered sequentially in the bottom right corner so that both text and attachments bear consecutive numbering. If necessary, the pagination uses alphabetical sequencing following a number. Whenever the text references an attachment, a cross-reference will be provided to the section where the attachment can be found.

For ease of reference, the entire amendment is numbered sequentially in the bottom right corner so that both text and attachments bear consecutive numbering. If necessary, the pagination uses alphabetical sequencing following a number. Whenever the text references an attachment, a cross-reference will be provided to the section where the attachment can be found.

CENTER FOR DRUG EVALUATION AND RESEARCH
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Three copies of the amendment are filed: an archival copy (in blue folder), a technical review copy (in red folder), and field copies (in maroon folders). The technical review copy and the field copies are identical to the archival copy and a certification attesting to this is provided in the Field Copy Certification.

Correspondence related to this proposal should be addressed to Marianne Robb, Mallinckrodt Inc., 675 McDonnell Blvd., St. Louis, Missouri 63134. If there are any questions concerning this information, please contact myself or James Baker (314-654-5729).

Sincerely,

Marianne Robb
Manager, Regulatory Affairs
(314) 654-6258
Fax (314) 654-6496

MALLINCKRODT

Mallinckrodt Inc. 675 McDonnell Blvd. P.O. Box 5840 St. Louis, MO 63134 Phone: (314) 654-2000 Fax: (314) 654-6496

MAJOR AMENDMENT

AMENDMENT

N|PC

September 30, 1999

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Attention: Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

RE: ANDA 40-352: Meperidine Hydrochloride Tablets, USP (50 mg and 100 mg)

Dear Sir or Madam:

The attached information is provided in response to the August 2, 1999 facsimile from the Agency in reference to ANDA 40-352 as submitted December 23, 1998 and amended March 22, 1999. Pursuant to Section 505(j) of the Food Drug and Cosmetic Act, Mallinckrodt Inc. submitted ANDA 40-352 seeking approval to market Meperidine Hydrochloride Tablets, USP (50 mg and 100 mg). Meperidine Hydrochloride Tablets, USP (50 mg and 100 mg) are a Schedule II prescription drug indicated for the treatment moderate to severe pain.

Meperidine Hydrochloride Tablets, USP (50 mg and 100 mg) will be manufactured, processed, packaged, labeled, and tested for release and stability at the Hobart, New York facilities. The packaged product will be held and distributed by Mallinckrodt Inc. at Mallinckrodt & Second Streets in St. Louis, Missouri.

The archival copy (one volume) is provided in a blue folder and the technical review copy (one volume) is provided in a red folder. This also certifies that, per 21 C.F.R. §314.440(a)(4) and concurrently with the filing of this amendment, true copies of the technical sections of the ANDA (maroon folders) were sent to the local district offices. Duplicate field copies have been provided to the Buffalo New York District Office and the St. Louis district office. For more detailed information on the organization of this amendment, please refer to the "Executive Summary" which is included immediately following the Table of Contents.

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Correspondence related to this submission should be addressed to Marianne Robb, Mallinckrodt Inc., 675 McDonnell Blvd., St. Louis, Missouri 63134. If there are any questions concerning this information, please contact myself or Robert Lake, Ph.D. at (314) 654-6125.

Sincerely,

Marianne Robb
Manager, Regulatory Affairs
(314) 654-6258
Fax (314) 654-6496

MALLINCKRODT

Mallinckrodt Inc.
675 McDonnell Boulevard
PO Box 5840
St. Louis MO 63134
Phone: 314.654.2000

ORIGINAL APPLICATION

December 23, 1998

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Attention: Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

RE: Meperidine Hydrochloride Tablets, USP (50 mg)

Dear Madame or Sir:

Mallinckrodt Inc. hereby submits this Abbreviated New Drug Application under 21 C.F.R. § 314.92(a)(1). This ANDA is for Meperidine Hydrochloride Tablets, USP (50 mg), a Schedule II prescription drug indicated for the relief of moderate to severe pain. Meperidine Hydrochloride Tablets, USP (50 mg) will be manufactured, processed, packaged, labeled, and tested for release and stability by Mallinckrodt Inc. at Mallinckrodt's facility in Hobart, New York. The packaged product will be held and distributed by Mallinckrodt Inc. at Mallinckrodt & Second Streets in St. Louis, Missouri.

This application consists of three volumes. An archival copy is being filed in blue folders and a technical review copy is being filed in red folders. A separate copy of the bioequivalence section is being submitted in an orange folder. This also certifies that, per 21 C.F.R. §314.440(a)(4) and concurrently with the filing of this ANDA, true copies of the technical sections of the ANDA were sent to the local district offices. These "field copies" are contained in maroon folders. For more detailed information on the organization of this application, please refer to the "Executive Summary" which is included immediately following the Table of Contents.

In addition, it is Mallinckrodt's intention that an electronic submission will arrive within 45 days of this paper application. In the event review of the paper submission is initiated before the electronic submission is received and processed, it is Mallinckrodt's understanding the review will be completed using the hard copy only.

Correspondence related to this submission should be addressed to Marianne Robb, Mallinckrodt Inc., 675 McDonnell Blvd., St. Louis, Missouri 63134. If there are any questions concerning this information, please contact myself or Robert Lake, Ph.D. at (314) 654-6125.

Sincerely,

Marianne Robb
Manager, Regulatory Affairs
Phone: (314) 654-6258
Fax: (314) 654-6496

MALLINCKRODT

Mallinckrodt Inc.
675 McDonnell Boulevard
PO Box 5840
St. Louis MO 63134
Phone: 314.654.2000

AMENDMENT TO A PENDING APPLICATION

March 22, 1999

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Attention: Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

RE: ANDA 40-352: Meperidine Hydrochloride Tablets, USP

Dear Madame or Sir:

Mallinckrodt Inc. hereby submits this amendment to the above referenced application under 21 C.F.R. §314.60(a). ANDA 40-352 is for Meperidine Hydrochloride Tablets, USP, a Schedule II prescription drug indicated for the relief of moderate to severe pain. This amendment provides for an additional strength, Meperidine Hydrochloride Tablets, USP (100 mg), to be manufactured, processed, packaged, labeled, and tested for release and stability by Mallinckrodt Inc. at Mallinckrodt's facility in Hobart, New York. The packaged product will be held and distributed by Mallinckrodt Inc. at Mallinckrodt & Second Streets in St. Louis, Missouri.

This amendment consists of three volumes. An archival copy is being filed in blue folders and a technical review copy is being filed in red folders. A separate copy of the bioequivalence section is being submitted in an orange folder. This also certifies that per 21 C.F.R. §314.440(a)(4) and concurrent with the filing of this ANDA, true copies of the technical sections of the ANDA were sent to the local district offices. These "field copies" are contained in maroon folders. For more detailed information on the organization of this application, please refer to the "Executive Summary" which is included immediately following the Table of Contents.

In addition, it is Mallinckrodt's intention that an electronic submission will arrive within 30 days of this paper application. In the event review of the paper submission is initiated before the electronic submission is received and processed, it is Mallinckrodt's understanding the review will be completed using the hard copy only.

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GENERIC DRUG

Correspondence related to this submission should be addressed to Marianne Robb, Mallinckrodt Inc. 675 McDonnell Blvd., St. Louis, Missouri 63134. If there are any questions concerning this information, please contact myself or Robert Lake, Ph.D. at (314) 654-6125.

Sincerely,

Marianne Robb
Manager, Regulatory Affairs
Phone: (314) 654-6258
Fax: (314) 654-6496